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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,181	07/26/2001	Felix Theeuwes	DURE-023	9651

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EXAMINER	
LAM, ANN Y	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/917,181	THEEUWES ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,6-13,19-22,24,25 and 29-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,6-13,19-22,24,25 and 29-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 6-13, 19-20, 22, 24, 25, 29 and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolinsky et al. 5,087,244.

Wolinksy discloses an elongate body (10) comprising a proximal end defining an inlet, and a distal end defining an outlet, the elongate body defining a lumen in the elongate body, said lumen extending between the proximal and distal ends;

and a diffuser element (16) operatively associated with the elongate body so as to define a diffusion space (i.e., space within element 16), wherein the elongate body distal end outlet is disposed in and in fluid communication with the diffusion space, and wherein the diffusion space is drug-permeable and water-permeable to provide for dilution of a drug in the diffusion space. (The device is capable of providing for dilution of a drug. For example, when fluid pressure from the source of medicine is discontinued, some fluid from the patient's body may enter element 16. Or when the balloon is deflated by aspirating through the inflation/deflation lumen to cause the balloon to collapse, some fluid from the patient's body may enter element 16.)

As to claim 2, the diffuser element (16) comprises a semipermeable membrane, a microporous membrane or an ion exchange membrane. (The element 16 has minute holes (29)

that is considered semipermeable since it allows through medicine or fluid but not substances that are larger than the size of the holes.)

As to claim 4, the distal outlet of the elongate body is defined by an exit orifice (20) of a drug delivery device and the diffuser element (16) is considered a cap in which the exit orifice is disposed since element (16) is at the distal end of elongate body.

As to claim 6, the diffusion space is defined by an outer wall of the elongate body (10) and an inner wall of the diffuser element (16), (see lumen at and near 20, Figure 2.)

As to claim 7, said diffuser element (16) envelops at least a portion of said elongate body (10), see Figure 2.

As to claim 8, the diffuser element is microporous, (column 4, lines 1-2.)

As to claim 9, the diffuser element is considered a dense membrane, (see column 5, lines 22-24, and lines 49-51.)

As to claim 10, the diffuser element is an ion-exchange membrane, (column 4, lines 1-2) since the holes (29) are capable of allowing an exchange of ions.

As to claim 11, said diffuser element distal end extends distally beyond the elongate body distal end, see Figure 2.

As to claim 12, the diffuser element distal is ring-shaped element, see Figure 2.

As to claim 13, the diffuser element is selectively permeable to water (column 4, lines 3-5.)

As to claim 18, the elongate body defines at least two lumens within the elongate body (18 and 26).

As to claims 19 and 24, the elongate body lumen is adapted for delivery of agent at a low volume rate, (column 4, lines 19-24.)

As to claim 20, the device is operably attached to a drug delivery reservoir, (column 5, lines 25-26.)

As to claim 22, the drug is capable of being delivered in microliter or submicroliter quantities per day (column 4, lines 3-5.)

As to claim 29, the diffuser element comprises a polymeric film, (column 3, lines 47-49.)

As to claim 31, the elongate body is drug-impermeable, and the diffuser element is substantially impermeable to drug and selectively permeable to water. (Applicant has not recited exactly what drug or what biological fluids or components in biological fluids in the claims. The Wolinsky device is capable of allowing fluids through (see col. 4, lines 21-22), while preventing passage of a drug larger than the openings.

As to claims 24, 25 and 32, Wolinksy teaches use of the balloon catheter in the body of a patient (25-28.) When fluid pressure from the source of medicine is discontinued, some fluid from the patient's body may enter element 16. Or when the balloon is deflated by aspirating through the inflation/deflation lumen to cause the balloon to collapse, some fluid from the patient's body would enter element 16.

As to claim 33, the diffuser element is substantially impermeable to biological fluids or components of biological fluids (i.e., biological fluids or components of biological fluids that are larger than the size of the openings in the device). The Office notes that Applicant has not recited exactly what biological fluids or components of biological fluids.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolinsky et al., 5,087,244.

Wolinsky discloses the invention substantially as claimed (see above).

Wolinsky discloses that the "aggregate flow area defined by the holes 29 is selected so that under the general range of inflation pressures expected, the liquid flow through the holes will be very low, weeping in nature, and will not exceed a predetermined maximum flow rate in atmosphere. Although the foregoing configuration of holes is believed to be satisfactory for a wide range, and possibly most, if not all, medications or drugs to be delivered, it is possible that certain medications or drubs [believed by Examiner to be a misspelling for 'drugs'] may have viscosity and flow characteristics as might require modifications to the holes" (column 4, lines 19-29.)

Wolinsky however does not teach that the diffuser element has a Diffusion Coefficient value in the range between 4.1 x 10-6 and 3.3 x 10-5 ug/cm/sec. However, it would have been obvious to form the diffuser element in which the holes' size and spacing is selected such that it has the specific Diffusion Coefficient as claimed, since Wolinsky teaches that medications may have viscosity and flow characteristics that might require modifications to the holes.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolinsky et al., 5,087,244, in view of Aoki et al., 6,113,915.

Wolinsky discloses the invention substantially as claimed (see above). Wolinsky teaches a catheter for delivery drugs to a body member having a lumen (column 2, lines 49-53.) However, Wolinksky does not disclose that the catheter contains Baclofen.

Aoki teaches use of a small catheter to deliver baclofen to treat spasticity since the intrathecal space is generally wide enough to accommodate a small catheter (column 2, lines 41-45.) It would have been obvious to use the Wolinsky catheter to deliver baclofen to treat spasticity since the intrathecal space is generally wide enough to accommodate a small catheter, as taught by Aoki.

Response to Arguments

Applicant's arguments filed November 1, 2005 have been fully considered but they are not persuasive. Applicant argues that the Wolinsky's outlet orifice (28) at the distal end of the catheter shaft is not disposed within the balloon. This is not persuasive because the Office action states that the outlet orifice is at (20).

Applicant argues that the Wolinsky device does not allow for diffusion, i.e., passive movement of an agent. Applicant argues that once pressure in the Wolinksy device is discontinued, the holes close up. Applicant also argues that aspiration is also not passive diffusion.

The device of Wolinksy has structural elements and openings such that the device allows for passive diffusion, by the same way Applicant's invention allows for passive diffusion, that is,

by providing medicine in the tube with the tube inside a body. Also, there is no disclosure in the Wolinsky patent that teaches that once pressure is discontinued, the holes close up (i.e., there is no disclosure that the holes are actually a slit valve, or somehow close up with no pressure).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.

LONG V. LE
SUPERVISORY PATENT EXAMINER
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02/19/06